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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,417	09/24/2003	Jimin Zhang	THERUS.005CP1	9389

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EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT PAPER NUMBER

3768

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,417

Applicant(s)

ZHANG ET AL.

Examiner

Ellsworth Weatherby

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/25/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/25/2005 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4 and 12, applicant discloses:

The method of claim 3, wherein thermal delivery probe has an outer diameter of about 4-10 French or larger (30/34, lines 17-18).

The method of claim 11, wherein thermal delivery probe has an outer diameter of about 2-7 French or larger (31/34, lines 21-22).

The above underlined wording is undefined and gives the outer diameter a limitless range. The applicant should, therefore, amend the claim to limit the outer diameter to a specific range.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3,6,7,10,11,14,15,18,19, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Driscoll et al. (USPN 5,882,302).

Regarding claims 1-3,6,7,10,11,14,15,18,19 and 21, Driscoll et al. '302 teaches a method for producing hemostasis using a HIFU thermal delivery probe located in the distal portion of the probe while imaging the site using Doppler ultrasound. Driscoll et al. '302 Discloses:

Methods and apparatus for the remote coagulation of blood using high-intensity focused ultrasound (HIFU) are provided. A remote hemostasis method comprises identifying a site of internal bleeding and focusing therapeutic ultrasound energy on the site, the energy being focused through an intervening tissue. An apparatus for producing remote hemostasis comprises a focused therapeutic ultrasound radiating

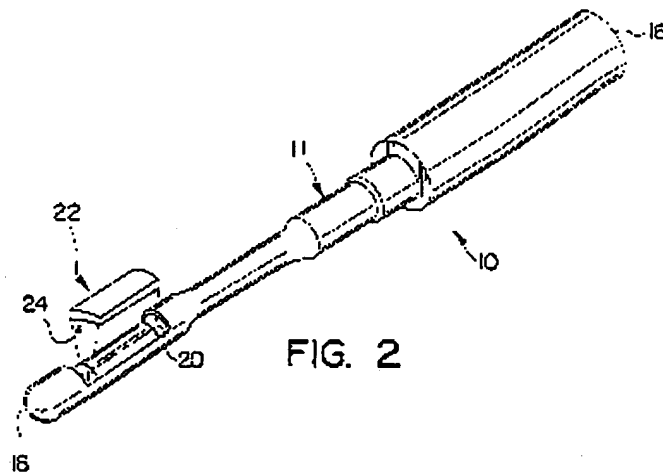
surface and a sensor for identifying a site of internal bleeding with a registration means coupled to the radiating surface and the sensor to bring a focal target and the bleeding site into alignment. The sensor generally comprises a Doppler imaging display. Hemostasis enhancing agents may be introduced to the site for actuation by the ultrasound energy (abstract).

In certain cases, such as vascular breaches in smaller blood vessels, hemostasis is provided by coagulating blood so as to form a plug within the vessel. Preferably, the therapy volume extends upstream of the vascular breach along the blood vessel, so that the plug occludes the vessel and reduces the release of blood (col. 5, lines 4-9).

Driscoll et al. '302 teaches raising the native tissue temperatures to cause the coagulation (col. 11, lines 15-17).

Driscoll et al. '302 further teaches the device having the ultrasound transducers in the distal portion of the probe:

Referring now to FIG. 2, probe 10 includes a probe housing 11 having a proximal end 16, a distal end 18 and an acoustic window 20. The probe housing is shown without a membrane over window 20 for clarity. The distal portion of housing 10 contains a transducer member having back-to-back active surfaces with focal geometries at a first and a second distance from the probe housing 11 about respectively (see FIG. 5). By rotating the transducer member within the housing and energizing the radiating surfaces independently, probe 10 is capable of applying HIFU therapy focused at a first distance 22 from housing 11 and also at a second distance 24 from housing 11 (col. 7, lines 56-67).



Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4,5,7-9,12,13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll et al. '302 in view of Seward et al. (USPN 5,713,363) in further view of Unger et al. (USPN 5,558,092).

Driscoll et al '302 discloses a percutaneous HIFU thermal delivery probe with Doppler ultrasound for producing hemostasis or coagulation (col. 5, lines 4-9). The device uses thermal energy that is ultrasonically emitted using the HIFU transducer that

has an acoustic window on the distal end of the device's elongated shaft (col. 7, lines 56-67).

Driscoll et al. '302 does not disclose the thermal delivery probe having an outer diameter of about 4-10 French or larger.

Seward et al. '363 teaches an ultrasound catheter having an outer diameter of about 4-10 French or larger. Seward et al. '363 discloses:

In the preferred embodiment, catheter body 22 preferably has a diameter of 4 to 24 French [one French divided by Pi equals one millimeter (mm)] and, more preferably, a diameter of 6 to 12 French (col. 4, lines 61-65).

Seward et al. '363 does not disclose the device operating at about 6 MHz and output about 2 W/cm².

Unger et al. '092 discloses a method for performing diagnostic and therapeutic ultrasound simultaneously using an ultrasound transducer array that can operate at about 6 MHz (col. 7, lines 60-65) and output about 2 W/cm² (col. 8, lines 37-41).

It would have been obvious to one of ordinary skill in the art to modify the method and providing apparatus of Driscoll et al. '302 with the catheter dimensions of Seward et al. '363 and the operational outputs taught by Unger et al. '092 for the purpose of minimizing vessel distension during the procedure and providing therapy within a safe and effective operational output range.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll et al. '302 in view of Belef et al. (USPN 6,078,831).

Driscoll et al '302 discloses as noted above.

Driscoll et al '302 does not disclose having a diagnostic ultrasound transducer adapted to interrogate a position in front of the thermal delivery probe.

Belef et al. '831 discloses an ultrasound guide wire having an ultrasound transducer adapted for forward-looking diagnostics (col. 6, lines 42-45).

It would have been obvious at the time the invention was made to modify the method and providing apparatus of Driscoll et al. '302 with the forward-viewing ultrasound diagnostics taught by Belef et al. '831 for the purpose of improving the physician's ability to direct the catheter to the therapy site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is 215 260 9852. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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